

### LYON & LYON LLP FILING RECORD

Attorney Docket No.:

254/304

Today's Date:

September 18, 2000

Attorney:

Suet M. Chong

Fee Transmitted Herewith:

None

Serial No.:

09/596,073

Filing Date:

June 16, 2000

Title:

**BIOADHESIVE PROGRESSIVE HYDRATION TABLETS** 

Inventor(s):

William J. Bologna et al.

## DOCUMENTS BEING FILED:

### THE PTO STAMP HEREON ACKNOWLEDGES RECEIPT OF:

Information Disclosure Statement Under 37 CFR § 1.97(b)(3) (1)

Form PTO-1449 (5 pages) (2)

LYON & LYON LLP

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Facsimile: (202) 331-3301

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:	)
William J. Bologna et al.	(0.16)
Serial No.: 09/596,073	(SFP:
Filed: June 16, 2000	2000 (5)
For: BIOADHESIVE PROHYDRATION TABLETS	GRESCHAR (THE )

Group Art Unit: Not Yet Assigned

Examiner: Not Yet Assigned

### INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.97(b)(3)

Commissioner for Patents Washington, D.C. 20231

Sir:

DC-2732.1

In accordance with 37 C.F.R. §§ 1.97 and 1.98, the items identified in this Information Disclosure Statement ("IDS") are brought to the attention of the Office. The items are listed on the attached form PTO-1449. Copies of all the items are not required to be provided because they were previously cited by or submitted to the Office in prior U.S. Patent Application No. 09/379,310 filed August 23, 1999.

The items identified in this IDS may or may not be "material" pursuant to 37 C.F.R. § 1.56. The submission thereof by Applicant is not to be construed as an admission that any such patent, publication or other information referred to therein is material or considered to be material (37 C.F.R. § 1.97(h)), or even qualifies as "prior art" under 35 U.S.C. § 102 with respect to this invention unless specifically designated by Applicant as such.

	CERTIFICATE OF MAILING
I hereby certify that this paper (along with any refebelow to the Commissioner for Patents, Washington	erred to as being attached or enclosed) is being hand delivered on the date shown on, D.C. 20231.
	Micheal A. Smith  Name of Person Delivering Paper
September 18, 2000	Medical Month

This IDS is believed to be timely in that it is being submitted under 37 C.F.R. § 1.97(b)(3), that is before the mailing of a first Office action on the merits. Thus, no petition or fee is required. However, if the undersigned is in error in this regard, then it is requested that the Office consider this IDS as filed under 37 C.F.R. § 1.97(c).

The Commissioner is hereby authorized to charge any fees required by the filing of these papers to Lyon & Lyon's Deposit Account No. 12-2475.

Respectfully submitted,

LYON & LYON LLP

Dated: September 18, 2000

By:

Suet M. Chong

Reg. No. 38,104

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### FORM PTO-1449

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## LIST OF PATENTS AND OTHER ITEMS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT

(Use several sheets if necessary)

ATTY. DE ET NO. 254/304

SERIAL NO. 09/596,073

APPLICANT:

William J. Bologna et al.

FILING DATE: June 16, 2000 GROUP:

Not Yet Assigned

			U.S.	PATENT DOCUMENTS
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME CLASS CLASS DATE
	AA	4,389,393	6/21/83	Schor et al.
	AB	4,540,566	9/10/85	Davis et al. (SEP 1 8 2000 CS)
	AC	4,596,795	6/24/86	Pobinson
	AD	4,615,697	10/7/86	Robinson
	AE_	4,764,378	8/16/88	Keith et al.
	AF	4,900,552	2/13/90	Sanvordeker et al.
	AG	5,102,666	4/7/92	Acharya
	AH	5,110,605	5/5/92	Acharya

			FOREIG	N PATENT DOCUMENTS				
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS	TRANS YES	LATION NO
	AI	06-100466	4/12/94	Japan (Abstract)				
	AJ	0 159 604 A2	10/30/85	Europe				
	AK_	0 654 261 A	5/29/95	Europe				

	·	OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.)
	AL	Voorspoels et al., "Buccal Absorption of Testosterone and its Esters Using a Bioadhesive Tablet in Dogs," Pharmaceutical Research, Vol. 13, No. 8, 1996; pp. 1228-1232.
	AM	Kim et al., Contraception, 1995, 52, pp. 314-316.
	AN	Dobs et al., <i>JCE&amp;M</i> 1998, Vol. 83, No. 1, pp. 34-39.
:	AO	Pitha et al., "Hydrophilic Cyclodextrin Derivatives Enable Effective Oral Administration of Steroidal Hormones," <i>Journal of Pharmaceutical Sciences</i> , Vol. 75, No. 2, February 1986, pp. 165 and 167.
	AP	PCT International Search Report for PCT/US99/19260, dated 2/10/2000.

EXAMINER: DATE CONSIDERI	ED:

### FORM PTO-1449

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			U.S. I	PATENT DOCUMENTS			
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE
	AA	5,554,380	9/10/96	Cuca et al.			
	AB	5,624,677	4/29/97	El-Rashidy et al. SEP 1 8 2000	705		
	AC	5,650,192	7/22/97	,	الما		
	AD	5,656,284	8/12/97	Britton et al.  Balkin			
	AE	5,686,094	11/11/97	Acharya			
	AF	5,750,134	5/12/98	Scholz et al.			
	AG	5,750,136	5/12/98	Scholz et al.			
	AH	5,780,045	7/14/98	McQuinn et al.			

			FOREIG	N PATENT DOCUMENTS				
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS	TRANS YES	LATION NO
	AI	0 488 139 A	6/3/92	Europe	:			
	AJ	0 273 209A		Europe				
	AK							

	OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.)
AL	Conway et al., "Randomized clinical trial of testosterone replacement therapy in hypogonadal men," Int'l J. of Andrology, 1988, 11, pages 247-264.
AM	Written Opinion (PCT Rule 66) related to International Application No. PCT/US99/19260, dated June 9, 2000.
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**DATE CONSIDERED:** 

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			U.S. I	PATENT DOCUMENTS			
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE
	AA	5,783,212	7/21/98	Fassihi et al.			
	AB	5,800,832	9/1/98	Tapolsky et al. (SEP 1 8 200	(C)		
	AC	5,804,209	9/8/98	De Ponti et al.	(S)		
	AD	5,807,575	9/15/98	Dumoulin et al.			
	AE	5,853,762	12/29/98	Myers et al.			
	AF	5,855,905	1/5/99	Oettel et al.			
	AG	3,133,862	5/19/64	Wershaw et al.			
	AH	4,226,848	10/7/80	Nagai et al.			

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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS	TRANS YES	LATION NO	
	AI								
	AJ								
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5,783,208

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ATTY. D ET NO. 254/304

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			U.S. F	PATENT DOCUMENTS			
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	AA	4,572,832	2/25/86	Kigasawa et al.			
	AB	4,740,365	4/26/88	Yukimatsu et al.			
	AC	4,915,948	4/10/90	Gallopo et al.			
	AD	5,252,334	10/12/93	Chiang et al. SEP 1 8 2000	1056		
	AE	5,298,017	3/29/94				
	AF	5,362,498	11/8/94	Theeuwes et al.  Aiache			
	AG	5,766,620	6/16/98	Heiber et al.			

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· · · · · · · · · · · · · · · · · · ·	AI								
	AJ		·						
	AK								

Venkateshwaran et al.

7/21/98

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.)					
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	AA	5,958,458	9/1999	Norling et al.			
· · · · · · · · · · · · · · · · · · ·	AB _	6,017,521	9/1999	Robinson et al.			
	AC	5,458,884	10/17/95	Britton et al.	$\Delta$		
	AD	5,460,820	10/24/95	Ebert et al. 3000	C58		
	AE			Ebert et al.			
··	AF			*			
	AG						
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	AJ							
	AK							

1		OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.)
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